Claims 13, 14, 15, and 23 have been amended to correct their dependencies. This amendment does not narrow the scope of the claims, nor was it made for reasons related to patentability as the claims were clear and unambiguous as originally written. Claim 12 has been amended to refer to the 52 bp region and to the stem-loop structure. Claim 16 has been amended to refer to a "variant" of the DNA fragment. This amendment does not narrow the claim as twice-amended claim 16 is not narrower in scope than amended claim 16.

Claim 17 has been amended to refer to "transfecting a cell with one or more DNA fragments" as suggested by the Examiner. This amendment does not narrow the claim as it only makes the claim grammatically correct. Furthermore, this amendment was not made for patentability because the claim was clear as originally written. Claim 17 has also been amended to depend from new claim 26, which has been added to recite a DNA fragment further comprising a nucleic acid to be expressed.

Claim 18 has been amended to read "cell is a bacterial, yeast or fungal cell" as suggested by the Examiner. This amendment does not narrow the claim as it only makes the claim grammatically correct. Furthermore, this amendment was not made for patentability because the claim was clear as originally written.

Claim 19 has also been amended to depend from new claim 26, which has been added to recite a DNA fragment further comprising a nucleic acid to be expressed.

Claim 23 has been amended to delete one "virus" as suggested by the Examiner. This amendment does not narrow the claim as it only makes the claim grammatically correct. Furthermore, this amendment was not made for patentability because the claim was clear as originally written. Claim 23 was also amended to refer to the 52 base region and to the stem loop structure.

Claim 25 was amended to refer to claim 12 rather than claim 24 as claim 24 has been canceled without prejudice.

The specification is amended at page 3, line 15 to replace the phrase "in the manner shown in claim 1" with the text of the original claim 1.

New claim 26 was added to add an element to be expressed by the promoter of claim 12. Support for this amendment can be found through out the specification and at least at page 1, line 38 to page 2, line 2.

Support from these amendments can be found through out the specification.

IV. ARGUMENT

A. Objections

Claim 12 was objected to because the stem loop of SEQ ID NO:2 is the complement of the stem loop of SEQ ID NO:1. While claim 12 was amended to refer to the 52 base region and the stem loop mooting this objection, Applicants point out that the sequence in SEQ ID NO:2 is not the complement to the sequence in SEQ ID NO:1. A review of the corresponding sequence in SEQ ID NO:1 from nucleotides 941 to 971, corresponding to the stem loop region, shows that the stem sequence is the same as that set forth in SEQ ID NO:2, but the loop region is different. A closer look at Figure 2, the figure containing a diagram of the stem loop, indicates that there can be different loop sequences, one of which is the precise sequence of the loop in SEQ ID NO:1.

The objections to claim 17 because of the phrase "transfecting a cell one or more DNA fragments;" claim 18 for the phrase "cell is a bacteria, yeast or fungi cell;" and claim 23 because of the phrase "virus virus" are believed to now be moot in light of the non-narrowing claim amendments made herein. Withdrawal of these objections in light of the amended claims is respectfully requested.

With respect to the note in paragraph 8 of the present office action, Applicants note that there was a discrepancy in the marked up claim 3, and the amended claim 3. Applicants apologize and appreciate the careful reading of the amendment by the Examiner. Based on the Amendment of September 21, 2001, Applicants believe claim 3

to read, "CFDV virus DNA fragment according to Claim 1, characterized in that it encompasses the nucleotides 211 to 991 of SEQ ID NO:1, 409 to 991 of SEQ ID NO:1, 611 to 991 of SEQ ID NO:1 or 711 to 991 of SEQ ID NO:1, where, for the purpose of numbering the nucleotides, the 5'-end of the linearized DNA resulting from cleaving the circular CFDV DNA with the restriction endonuclease *Xho*I, has been assigned the position 1." If this is incorrect, Applicants request that the Examiner contact the undersigned.

The Examiner has objected to the alleged addition of new matter by Applicants' submission of the sequence of SEQ ID NO:1 into the specification. The Examiner states that Applicants have introduced new matter because Applicants failed to incorporate Rhode, Virology 176: 648-651, 1990 by reference, although Applicants clearly stated in the original specification that the sequence could be found in Rhode. Applicants assert that the addition of the sequence to the specification in the form of the submitted sequence listing is appropriate. The issue is whether there is support in the original specification for that which is claimed. The specification must include an adequate written description of the alleged new matter. However, this description need not be *in haec verba.* The standard for whether there is support in an application is based on whether a skilled artisan would understand that the subject matter was disclosed within the specification and whether the inventor was in possession of the claimed subject matter. There can be no doubt based on the specification that the sequence disclosed in Rohde was within the possession of the Applicants, or whether the Applicants intended to have the sequence of Rohde constitute part of the specification.

The application states,

> The CFDV virus is located in the vascular system of the plant (cf. J.W. Randles et al.: "Localization of coconut foliar decay virus in coconut palm", Ann. Appl. Biology 1992, 601-617). A DNA associated with the disease symptoms and the occurrence of viral particles has already been cloned, sequenced and its structure determined at an earlier point in time (cf. W. Rohde et al.: "Nucleotide sequence of a circular single-stranded DNA associated with coconut foliar decay virus", Virology 176: 648-651, 1990).

> CFDV is a viral phytopathogen with a genome consisting of covalently closed-circular simplex DNA. Rohde et al., Virology 176: 648-651, 1990 described a DNA molecule of CFDV with a size of 1291 nucleotides and deletion mutants thereof.

Application, page 2, lines 23-37. The specification also states,

> To generate CFDV DNA fragments according to the invention, the skilled worker resorts to well-known techniques such as, for example, suitable cleavage sites of restriction endonucleases on the CFDV DNA, or the polymerase chain reaction technique which allows, starting from a full-length CFDV DNA construct, CFDV DNA fragments of the desired length to be amplified by means of specific primers. To this end, the primers are synthesized to suit the desired CFDV fragment in a manner known per se, using the nucleotide sequence of the CFDV virus, more specifically the nucleotide sequences in the region of the 5'- or 3'-ends of the desired fragment, described by W. Rohde et al. in Virology 176: 648-651, 1990.

It is clear from these two passages that the Applicants intended for the sequence disclosed in Rohde to constitute part of the specification. Furthermore, the skilled artisan would understand the Rohde sequence to have been disclosed.

Recent case law supports the disclosure of the sequences from Rohde. In *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1325 *on rehearing*, (Fed. Cir. 2002), the Federal Circuit held that sequences are inherently described by reference to a deposit; therefore, a biological deposit satisfies the written description requirement. In *Enzo*, the patentee had not disclosed the sequence that was referred to in the claims. However, the patentee had deposited a molecule that possessed the sequence. Becaue the sequence was a part of the molecule deposited the court held that the claims were not invalid for failure to meet the written description requirement.

The present case is analogous to *Enzo*. The reference the Applicants made to a molecule was a molecule having a particular sequence that was easily known or could be determined, and the Applicants intended that the molecule and/or its sequence constitute part of the specification. In fact, the present facts contained even more information, than that presented by the patentee in *Enzo*. The present Applicants point to a specific sequence. In *Enzo*, the patentee merely pointed to a molecule, the sequence of which needed to still be determined.

The claimed sequence is inherently described by reference to Rohde. As in the case of biological deposits, one of skill in the art reading the references to Rohde in the specification is readily able to obtain the Rohde article. Like *Enzo,* the sequence in the present case is publicly available and the specification specifically discloses exactly where one of skill in the art can find the specific sequence. Furthermore, the Rohde sequence is unalterable as it has already been published.

One of skill in the art would know that the Applicants were in possession of the claimed sequence by seeing the reference to Rohde in the specification and reading the disclosure of Rohde. Therefore, the inclusion of the sequence disclosed in Rohde is not an addition of new matter because the sequence was already a part of the specification, as one of skill in the art would understand it, and this is the standard by which one must judge the sufficiency of the disclosure. Therefore, Applicants respectfully request withdrawal of the objection.

B. Rejection under 35 U.S.C. § 112, second paragraph

Claims 11, 13, 15, 16, 17-21, 24, 25 were rejected under35 U.S.C. § 112, second paragraph for allegedly being indefinite and failing to particularly point out the claimed subject matter.

The PTO rejected claims 11, 13, 15, and 24 under 35 U.S.C. § 112, second paragraph, because "there is insufficient antecedent basis for "DNA fragment according

to claim 1." Claims 11, 13, 15, 16, 17-21, 24, and 25 have now been amended to correct their dependencies, mooting this rejection. Withdrawal of this rejection in light of the amended claims is respectfully requested.

The PTO rejected claim 16 because it is allegedly unclear. Claim 16 has been amended to remove the "conserved" language, mooting the Examiner's concerns. Claim 16 is directed to "A DNA fragment, which is a variant of the sequence set forth in SEQ ID NO:1 or fragment thereof wherein the fragment is a modified promoter which does not have an activity 20% more than or 20% less than the promoter activity of nucleotides 211-991 of SEQ ID NO:1." One of ordinary skill in the art would readily understand the phrase "a modified promoter which does not have an activity 20% more than or 20% less than the promoter activity of the nucleotides 211-991 of SEQ ID NO:1" to mean that the DNA fragment of claim 16 demonstrates promoter activity which is within 20% of the promoter activity of the starting fragment.

The Examiner has indicated that only certain fragments meet the claim limitations. Applicants are not sure precisely what the Examiner is concerned with. Support for this claim can be found throughout the specification, for example at page 5, lines 16-24. Furthermore, the specification discloses specific examples that meet this claim limitation as demonstrated in Table 2 and Table 3. As the Examiner recognized, these Tables disclose at least four constructs according to the invention. Therefore, the claims are clear and unambiguous as written.

With respect to the Examiner's concerns as to whether one of skill in the art could identify molecules that fall within the claims, the answer, as demonstrated by the specification is clearly yes. Applicants have provided the methods needed to determine whether a particular fragment has an activity 20% more or 20% less than the promoter activity of nucleotides 211-991 of SEQ ID NO:1, and as demonstrated by the data, molecules having this level of activity exist.

Claims 17-20 were rejected as being incomplete for allegedly omitting essential items. New claim 26 was added, drawn to claim 12, further comprising a nucleic acid to be expressed, wherein the nucleic acid is operably linked to the DNA fragment. Claims 17 and 19 were amended to depend from claim 26 rather than claim 12. It is believed this addresses the Examiner's concerns.

Claim 21 has been canceled without prejudice, and the objection to claim 21 should now be mooted.

The PTO rejected claim 25 because it allegedly depends from itself. Claim 25 has been amended to depend from claim 12. However, prior to this amendment, claim 25 depended from claim 24. Specifically, claim 25 read: "The DNA fragment of claim 24, wherein the DNA fragment further comprises nucleotides 655 to 676 and 682 to 701 of SEQ ID NO:1. As is readily apparent, claim 25 does not depend from itself. Therefore, it is clear what the metes and bounds of the claim are and allowance of claim 25 is respectfully requested.

C. Rejection under 35 U.S.C. § 112, first paragraph

1. Introduction

The disclosed subject matter revolves around promoters that can function in both monocot an dicot plants, as well as in the phloem tissue of plants. As discussed in the specification, the function requires two structural elements: 1) the stem loop region of the CFDV DNA and 2) the absence of at least one of the translation start sites for either ORF1 and/or ORF2. The Applicants have provided examples of many variants of the disclosed promoter regions that have the required elements. The Examples support the assertion that the only required elements are these two elements.

2. Enablement

The PTO rejected claims 12, 13, 16, 17, and 22 for allegedly being non-enabled. The Examiner primarily seems concerned that given the nature of the invention and the state of the art, the specification 1) does not provide enough guidance for the breadth of

the claims and 2) the specification lacks working examples to support the breadth of the claims.

Section 112, first paragraph requires that the patent specification enable those skilled in the art to make and use the full scope of the claimed invention without undue experimentation. The specification is fully enabling for each of the claims because one of skill in the art would understand how to make and use the full scope of the claimed invention without undue experimentation.

a) Stem-loop

Independent claim 12 has been amended to include a 52bp stretch required for promoter activity. Support for this amendment can be found throughout the specification as demonstrated above. Therefore, Applicants' base claim now identifies a specific region, in addition to the stem loop, which is necessary for increased promoter activity.

While Applicants have amended the claim to include the 52 base region, Applicants maintain that the stem-loop region is necessary for activity from the disclosed promoters in plants, but not bacteria. This is evidenced by the fact that removal of the stem loop region drastically reduces activity, as shown by the constructs in Tables 2 and 3.

The claims are fully enabled for a CFDV virus fragment of at least nucleotides comprising position 711-991 of SEQ. ID. NO:1. The Examiner recognizes that the specification is enabling for such fragments. Therefore, the PTO admits that the specification teaches that which is claimed. It is believed that the amendments to claims 12 and 23 address the Examiner's concerns regarding claims drawn to fragments comprising the stem-loop, but Applicants maintain the right to prosecute claims comprising just the stem-loop in a related application.

b) Variants

Claim 16 is fully enabled. Claim 16 has been amended to refer to variants rather than conserved variants, notwithstanding the fact that in the context of nucleic acids conserved variants could be considered, for example, conserving purines or pyrimidines at a particular location. One of skill in the art would understand how to make the full scope of claim 16 from the disclosure in the specification. Variants are described throughout the specification, particularly in Fig. 2 of the specification. The ability to make nucleic acid variants is well understood by those of skill in the art, and the Applicants have provided a standard by which these variants can be tested. The legal standard is one of undue experimentation and this standard is art specific, meaning what is undue experimentation in one field need not be undue experimentation in another, and does not preclude testing. For example, the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *M.I.T. v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 190 U.S.P.Q. 214 (CCPA 1976).

The facts underlying the decision of *In re Wands* illustrate well the concepts put forth in *MIT. A.B. Fortia* and *In re Angstadt.* The method claims at issue in *Wands* involved the use of an antibody wherein the "antibody is a monoclonal high affinity IgM antibody having a binding affinity constant for . . . [the antigen] of at least $10^9 M^{-1}$." *In re Wands*, 858 F.2d at 734. This claim covers *any* monoclonal antibody, not just a specific monoclonal antibody, and the PTO argued that the Applicants failed to enable *all* monoclonal antibodies. *Id.* Briefly, the skilled artisan generates monoclonal antibodies by injecting an antigen into a host animal causing an immune reaction, isolating spleen cells, some of which produce the antibodies that bind the antigen, fusing the spleen cells with a cancerous myeloma cell producing a hybridoma, and then screening individual hybridomas to isolate those that produce antibodies that bind the antigen. *Id.* at 733-734. The PTO supported its non-enablement position by pointing out that 1) not all

hybridomas produce antibodies that bind antigen, 2) not all hybridomas that bind antigen will bind with an affinity of $10^9 M^{-1}$, and 3) the Applicants own data indicated that a small percentage of hybridomas actually produced monoclonal antibodies which fell within the scope of the claims. *Id.* at 738-739. The court rejected these arguments by stating,

> cell fusion [hybridoma technology] is a technique that is well known to those of skill in the monoclonal antibody art, . . .[t]here was a high level of skill in the art at the time when the application was filed, and all the methods needed to practice the invention were well known . . . [and] it seems unlikely that undue experimentation would be defined in terms of the number of hybridomas that were never screened, . . .[and since] Wands carried out his entire procedure three times , and was successful each time in making at least one antibody that satisfied all of the claim limitations . . . Wands evidence thus effectively rebuts the examiner's challenge to the enablement of their disclosure.

Id. at 740. Furthermore, the Wands court made clear that the amount of and type of experimentation considered undue fluctuates for each type of art. *Id.* The quantity of experimentation lacks relevance outside an assessment of what is "routine experimentation" in the art. *Id.* Thus, the huge amount of "experimentation" that the skilled artisan would have to perform to practice Wands' invention: immunizing an animal, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening the hybridomas for the desired characteristics, *knowing that many hybridomas would not produce functional antibodies and* ***not*** *knowing which hybridomas would produced claimed antibody*, was not undue experimentation because it was routine experimentation in the art of monoclonal antibody production. *Id.*

As discussed below, the present claims and corresponding enablement rejection closely parallel the situation presented in *Wands* since the art of producing variants of a promoter is routine experimentation in the art of nucleic acid expression, once the standard is described, as done here by the Applicants, even though it may seem complex.

c) Enabled for the Skilled artisan at the filing date

An application must be read through the eyes of the person of ordinary skill in the art1 and information known to one of ordinary skill in the art may be relied upon for purposes of the enablement analysis. *In re Glass*, 492 F.2d 1228, 1232 (Fed. Cir. 1974).2 A patent application preferably omits that which is well-known or common knowledge to those of ordinary skill in the art.3 Thus, an applicant should not be penalized for leaving out information in his patent application that those of ordinary skill in the art knew or could readily have obtained at the time of the filing of the patent application. The specification must be enabled at the time of filing the application. *In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993).

d) The skilled artisan knows that which is available

The skilled artisan knows the fundamental knowledge specific to the particular art and the places and ways to search out particularized information. *In re Howarth*, 654 F.2d 103 (C.C.P.A. 1981). Thus, English publications and US patents are part of the skilled artisans knowledge.

Surely the Examiner is not suggesting that Applicants should have provided all of the information known about how to make variants and test them. Applicants have provided what is required. They have shown that the very small fragments, lacking the open reading frame start site function. Once this knowledge is gained, making the next variant and comparing it to the disclosed variants is not undue experimentation.

Applicants have provided data demonstrating that variation across the full scope

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[1] "Patents . . . are written to enable those skilled in the art to practice the invention, not the public." *W.L. Gore & Assoc., Inc. V. Garlock, Inc.* 721 F.2d 1540, 1556 (Fed. Cir. 1983) (citing *In re Stores*, 245 F.2d 474, 478 (CCPA 1957))

[2] See also *In re Mott* 539 F.2d 1291, 1296 (Fed. Cir. 1976) stating, "The evidence upon which appellant may rely to show what meaning persons skilled in the art would attribute to his disclosure for the purposes of § 112 and § 132 is that which pertains to the *public* knowledge extant on appellant's effective filing date." (emphasis in original).

[3] "[A] . . . specification need not disclose what is well known in the art." (*Lindemann Maschinenfabrik v. Am. Hoist and Derrick,* 730 F.2d 1452, 1463 (Fed. Cir. 1984) (citing *In re Myers*, 410 F.2d 420 (CCPA 1969). See also *Hybritech Inc. v. Monoclonal Antibodies, Inc.*802 F.2d 1367, 1384 (Fed. Cir. 1986).

of the claims of SEQ ID NO:1 will still achieve the claimed promoter activity: deletion mutants lacking nucleotides 211 to 411 of SEQ ID NO:1 work; deletion mutants lacking nucleotides 211 to 611 of SEQ ID NO:1 work; and even deletion mutants lacking nucleotides 211 to 711 of SEQ ID NO:1 work. One of skill in the art would readily appreciate that Applicants' data indicate not only that deletion mutants will work, but also how to arrive at the specific constructs without undue experimentation.

There is clear indication in the specification that the variants are considered disclosed. The specification states,

> Equally, the invention relates to DNA fragments which are derived from the above-defined CFDV fragments by substituting, deleting, inserting or modifying individual nucleotides or smaller groups of nucleotides and have a promoter activity which is comparable with that of the starting fragments, and their use as promoters. A comparable promoter activity can be, for example, a promoter activity which is up to 20% higher or lower than that of the starting fragment.

Page 5, lines 16-24. The specification also provides specific examples for creating constructs according to the invention in tobacco protoplasts and *E. coli.* (see specification at pages 11- 15).

The specification is fully enabled for variants of the disclosed fragments. One of skill in the art can make and use the variants. Applicants respectfully request reconsideration of the claims for lack of enablement.

e) Use of the DNA fragments

Furthermore, one of skill in the art would readily appreciate that claims directed to bacterial, yeast, or fungal cells and could easily be modified for use in transgenic plants, parts of plants and transformed plants. Furthermore, the necessary modifications are fully within the skill of the art. Such modifications would encompass little or no experimentation, and certainly would not rise to the level of "undue experimentation" as required under § 112. As discussed above, it is preferable that the Applicant omit that

which is known in the art. The specification clearly indicates that there is significant knowledge in the art about transfecting a variety of organisms, including plants. The specification states,

> It is generally known that genetic engineering techniques allow individual genes to be transferred into the genome of organisms, such as microorganisms, yeasts or plants, in a targeted manner. This technique, which is known as transformation or, in the case of higher cells, also as transfection, is carried out routinely by various routes, for example by particle gun bombardment (cf. M.E. Fromm, F. Morrish, C. Armstrong, R. Williams, J. Thomas and T.M. Klein: "Inheritance and expression of chimeric genes in the progeny of transgenic maize plants", Bio/Technology 8: 833-839, 1990), naked DNA transfer (cf. P. Meyer, I. Heidmann, G. Forkmann and H. Saedler: "A new petunia flower colour generated by transformation of a mutant with a maize gene", Nature 330: 677-678, 1987) or by Agrobacterium-mediated stable integration of genes or gene segments into the genome of a recipient plant.

Page 1, lines 7-23. The specification provides ample guidance to make the claimed transfected and transformed cells.

Contrary to the position of the PTO, the specification provides ample guidance and working examples allowing one of skill in the art to make and use the full scope of the claims. Therefore, withdrawal of the rejections and allowance of the claims is respectfully requested.

3. Written Description

The PTO rejected claims 16 and 22 for allegedly lacking written description. The written description requirement of section 112 is met if one of ordinary skill in the art would understand from the specification that the inventor was in possession of the claimed subject matter. The claimed molecules are fully described because, as is shown in the specification, various molecules having the claimed attributes are disclosed and the

skilled artisan, given the knowledge in the art and that which is disclosed in the specification would recognize possession by Applicant.

a) The Legal Standard

While it is clear that an application must contain a "written description" of the claimed invention, (35 U.S.C. § 112, first paragraph) the compliance with this standard still confuses. Most understand that clear conveyance that applicant has invented the claimed subject matter stands as the essential goal of the written description requirement, but still, even after clear federal circuit instruction, the standard gets misapplied. *See In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977) and *Enzo Biochem v. Gen-Probe*, 296 F.3d 1316, 1324 (Fed. Cir. 2002) (hereafter, "*Enzo II*"). The federal circuit has described this goal as "putting the public in possession" of what the applicant claims as the invention. See *Vas-Cath v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991) (hereafter "Vas-Cath") and *The Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1566; 43 USPQ2d 1398, 1404 (Fed. Cir. 1997) (hereafter, "*Lilly*").

The following discussion on the legal standard for the written description requirements aims to show that the standard does not require the structure of biological molecules.

(1) The written description requirement does not require the structure of biological molecules

A number of years of jurisprudence on the written description requirement by the federal circuit culminated in its decision in *Lilly*. *Lilly* established that, in the *case of claims to genes*, an adequate written description requires more than the name of the gene and a statement of its function, if nothing more was known about the gene. *Lilly*, 119 F.3d at 1168; 43 USPQ2d at 1406. Since the claims in *Lilly* were to *the gene*, the court required some physical description of the gene (such as its nucleotide sequence). While the PTO clearly understood, as evidenced by their publishing of the Guidelines, that the federal circuit did not hold that *any* recitation of a biological molecule requires a

recitation of the structure of that molecule, such as the sequence, unfortunately for patent applicants this has become the defacto interpretation. Guidelines for Examination of Patent Applications Under 35 U.S.C. 112, ¶1 "Written Description" Requirement, 66 Fed. Reg. 1,099 (Jan. 5, 2001) (hereafter, "Written Description Guidelines").

The Patent Office undertook a review of the written description case law in view of *Lilly* in order to establish the Guidelines for compliance with the written description requirement of 35 U.S.C. § 112, first paragraph. Far from requiring any absolute or *per se* requirement for adequate written description, the resulting Guidelines provide a case-specific and fact-dependant inquiry, which case law supports. *See, e.g., Vas-Cath* , 935 F.2d 1555 (Fed. Cir. 1991).

Perhaps the clearest statement that structure is not necessary, and one carrying the most weight, comes from *Enzo II.* The federal circuit in *Enzo II* stated,

> It is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement. The PTO has issued Guidelines governing its internal practice for addressing that issue. The Guidelines, like the Manual of Patent Examining Procedure ("MPEP"), are not binding on this court, but may be given judicial notice to the extent they do not conflict with the statute. *See Molins PLC v. Textron, Inc.,* 48 F.3d 1172, 1180 n. 10, 33 USPQ2d 1823, 1828 n. 10 (Fed.Cir.1995). In its Guidelines, the PTO has determined that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... *i.e.,* complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure,* or some combination of such characteristics." *Guidelines,* 66 Fed.Reg. at 1106 (emphasis added). For example, the PTO would find compliance with 112, 1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature. Synopsis of Application of

Written Description Guidelines, at 60, *available at* http:// www.uspto.gov/web/patents/guides.htm (*Application of Guidelines*).

Enzo II. Thus, structure is not required to meet the written description standard and the federal circuit clearly has adopted at least the Guidelines in so far as their application to antibodies is concerned. This is very similar to the technology at issue. We have examples, we know how to find them, and amount of work needed to find them is considered routine in the art. Applicants respectfully request reconsideration of the claims as the claims are fully described.

D. Rejection under 35 U.S.C. § 102

The PTO rejected Claims 16 and 23 as allegedly being anticipated by Rhode. Each and every claim limitation must appear in the prior art reference for the claim to be anticipated. The Examiner points out that Rhode discloses a CFDV fragment (Xhol-Sty 1) which comprises a stem-loop structure, but not a ORF-2 translation start site. The Examiner contends that instant Table 3 shows that in *E. coli*, the Xhol-Sty1 fragment has a promoter activity that is within 20% of that seen for the 211-991 fragment.

Claim 16 and claim 23 have been amended to refer to the translation start site for ORF 1. Applicants believe this traverses the rejection over Rohde. Reconsideration of the claims is respectfully requested.

E. Double Patenting

Claims 11-25 were rejected under the judicially crated doctrine of obviousness type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,303,345. Applicants will submit a Terminal Disclaimer as appropriate when the application is in condition for allowance.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

Payment in the amount of $920.00 is to be charged to a credit card and such payment is authorized by the signed, enclosed document entitled: Credit Card Payment Form PTO-2038. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

Gwendolyn D. Spratt

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, Washington, D.C. 20231 on the date shown below.

Gwendolyn D. Spratt

Gwendolyn D. Spratt

12-30-02

Date

Appendix A
Marked-up specification and marked-up claims

In the specification

Paragraph beginning on page 3, line 15:

It has been found that the [set] said object can be achieved with specific virus DNA fragments which are derived from the DNA of the CFDV virus [in the manner shown in Claim 1] DNA fragment which encompasses the stem-loop structure, but not the translation start for the open reading frame ORF1.

In the claims:

12. (Twice Amended) A [cocount] coconut foliar decay virus DNA fragment comprising [the stem-loop structure] nucleotides 734 to 785 set forth in SEQ ID NO:[2]1, and nucleotides 941 to 971 of SEQ ID NO:1, but not the translation start for the open reading frame ORF1 set forth as nucleotides 1004 to 1006 of SEQ ID NO:1, wherein the DNA fragment has promoter activity.

13. (Twice Amended) A [cocount] coconut foliar decay virus DNA fragment according to claim [1] 12, which additionally does not contain the translation start for the open reading frame ORF2 set forth as nucleotides 1215 to 1217 of SEQ ID NO:1.

14. (Twice Amended) A [cocount] coconut foliar decay virus DNA fragment according to claim [1] 12, wherein the DNA fragment further comprises nucleotides 655 to 676 and 682 to 701 of SEQ ID NO:1.

15. (Twice Amended) A [cocount] coconut foliar decay virus DNA fragment according to claim [1] 12, comprising the nucleotides 211 to 991 of SEQ ID NO:1, 409 to 991 of SEQ ID NO:1, 611 to 991 of SEQ ID NO:1 or 711 to 991 of SEQ ID NO:1.

16. (Twice Amended) A DNA fragment, which is a [conserved] variant of the sequence set forth in SEQ ID NO:1 or fragment thereof wherein the fragment is a modified promoter which does not have an activity 20% more than or 20% less than the promoter activity of nucleotides 211-991 of SEQ ID NO:1.

17. (Twice Amended) A method of expressing a nucleic acid comprising transfecting a cell with one or more DNA fragments according to Claim [12] 26.

18. (Twice Amended) The method of claim 17, wherein the cell is a bacterial, yeast or fungi cell.

19. (Twice Amended) A method of expressing a gene in a plant comprising transfecting one or more DNA fragments according to Claim [12] 26, wherein the expression is tissue specific.

21. (Twice Amended) A method of producing chimeric constructs comprising, [transfecting] operably linking one or more DNA fragments according to Claim 12 to a nucleic acid to be expressed.

22. (Twice Amended) A transgenic plant, part of a plant, transformed plant, yeast or bacterial cell[s] comprising a DNA according to Claim 12.

23. (Amended) A [cocount] coconut foliar decay [virus] virus DNA fragment comprising [the stem-loop structure] nucleotides 734 to 785 set forth in SEQ ID NO:[2]1, and nucleotides 941 to 971 of SEQ ID NO:1, but not the translation start for the open reading frame ORF2 set forth as nucleotides 1215 to 1217 of SEQ ID NO:1, wherein the DNA fragment has promoter activity.